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09/708,617	11/09/2000	Wilhelmus Joseph Leonardus Suyker	DVME-1005US	1725

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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,617	SUYKER ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,36,37 and 40-64* is/are pending in the application.

4a) Of the above claim(s) *10 and 58-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,36,37 and 40-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3-5,7,8,11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims currently under examination: 1-9, 36-37 and 40-57.

Drawings

The submission of formal drawings is acknowledged.

Specification

The amendments to the abstract are acknowledged.

Content of Specification
Applicant is reminded of the proper format for the specification.

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive; preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication, which adequately describes the subject matter.

(i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The title should include a novel feature of the invention since there are many deformable connectors for mechanically connecting hollow structures.

Election/Restrictions

2. Claims 10 and 58-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 recites, "a main plane of the annular member and the center line of the annular member that are at an angle relative to one another." However, it is unclear whether this position is in the starting position, the joining position, both positions, etc.

5. Claim 37 recites the limitation "the center line" in the last lines of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no prior recitation of a center line in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-7, 36-37, 40-43, and 46-51 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Berg et al. in US Patent No. 6,391,036.

Regarding claim 1, Berg et al. disclose a connector (seen in figure 21 for example) for mechanically connecting hollow structures having an annular member (such as that generally at 16/14) of deformable material having a center line and a main plane and permanently deformable by expansion from a first size in a starting position in which the connector is delivered to a desired anastomosis site to a second, larger size in a joining position in which the connector connects the hollow structures, as recited in column 2, lines 1-50, column 9, lines 1-28 and seen in figures 20 and 21 for example; joining elements (14) circumferentially spaced about the annular member (generally at 16/14) for joining abutting walls of hollow structures together, the joining elements having staple-like elements (portions of 14) which are permanently deformable form a starting position in which the connector is delivered to a desired anastomosis site to a joining position in which the staple-like elements (portions of 14) engage the hollow structures to thereby cause the connector to connect the hollow structures where each staple-like elements (portions of 14) is attached to the annular member and has at least two staple portions extending from the location of attachment between each staple-like element and the annular member to free ends of each staple portion, at least part of each staple portion being tapered in a direction corresponding to a direction form the location of attachment between each staple-like elements and the annular member towards the free ends of the staple portion, as recited in column 2, lines 1-51; column 4, column 5-6; column 9 and

seen in figures 1-23 with emphasis on figures 21 and 22. It is noted, that the center line and main plane have not been defined with respect to any axis.

Regarding claim 2, Berg et al. disclose that as applied to claim 1, as well as, each staple portion that tapers to at least a lesser radial thickness, as recited in column 9, lines 15-27 and seen in figures 20 and 21.

Regarding claim 3, Berg et al. disclose that as applied to claim 1, as well as, a center line of each of the staple-like elements that is disposed substantially within a radial plane of the annular member, as seen in figure 21.

Regarding claim 4, Berg et al. disclose that as applied to claim 2, as well as, staple-like elements that are substantially straight in their starting positions, as seen in figure 12 and would be prior to deployment.

Regarding claim 5, Berg et al. disclose that as applied to claim 3, as well as, staple portions of the staple-like elements that have extreme tips, in the starting position, that are curved to approximate an anticipated curve of the tips resulting from the deformation of the staple like elements form the starting position to the joining position, as recited in column 4, lines 40-45.

Regarding claim 6, Berg et al. disclose that as applied to claim 1, as well as, a connector that is made from one piece of material, as recited in column 4.

Regarding claim 7, Berg et al. disclose that as applied to claim 1, as well as, staple portion of at least some of the staple-like elements that are configured differently on opposite sides of the point of attachment between the staple-like elements and the annular member, as seen in figure 21 via the taper.

Regarding claim 36, Berg et al. disclose a connector for mechanically connecting hollow structures having an annular member (such as 16/14) of deformable material having a center line and a main plane and being permanently deformable by expansion from a first size in a starting position in which the connector is delivered to a desired anastomosis site, to a second, larger size in a joining position in which the connector connects hollow structures; and joining elements (generally at 14) that are circumferentially spaced about the annular member for joining abutting walls of the hollow structures together, the joining elements including staple-like elements (portions of 14) which are permanently deformable from a starting position in which the connector is delivered to a desired anastomosis site, to a joining position in which the staple-like elements (portions of 14) that engage the hollow structures to thereby cause the connector to connect the hollow structures; and a main plane of the annular member and the center line of the annular member that are at an angle relative to one another, as recited throughout the specification and seen in figures 1-23 with emphasis on columns 2, lines 1-51; column 4, column 8, column 9 and figures 21 and 22.

Regarding claim 37, Berg et al. disclose a connector for mechanically connecting hollow structures having an annular or tubular member (such as 16/14) of deformable material being adapted to be permanently deformed from a first size in a starting position in which the connector is delivered to a desired, to a second, larger size in a joining position in which the connector connects hollow structures; and joining elements (such as 14) that are circumferentially spaced about the annular or tubular member for joining abutting walls of the hollow structures together, the joining elements including staple-like elements (portions of 14) which are permanently deformable from a starting position in which the connector is delivered to a desired anastomosis site, to a joining position in which the staple-like elements engage the hollow structures to thereby cause the connector to connect the hollow structures where each staple-like element is attached to the annular member proximate to a center of the staple-like element and extends in a direction substantially parallel to a center line of the annular member, as recited throughout the specification and seen in figures 1-23 with emphasis on columns 2, lines 1-51; column 4, column 8, column 9 and figures 21 and 22.

Regarding claim 40, Berg et al. disclose that as applied to claim 1, as well as, tapering of the at least one staple portion that provides predetermined bending characteristics to the at least one staple portion, as recited in column 9, lines 1-26.

Regarding claim 41, Berg et al. disclose that as applied to claim 40, as well as, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a C-shape in the joining position, as seen in figure 22.

Regarding claim 42, Berg et al. disclose that as applied to claim 40, as well as, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a C-shape forming a circle in the joining position, as seen in figure 22.

Regarding claim 43, Berg et al. disclose that as applied to claim 40, as well as, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a C-shape forming overlapping circles in the joining position, as recited in column 4, lines 31-60.

Regarding claim 46, Berg et al. disclose that as applied to claim 1, as well as, tapering of the staple portions that is located on a radially outer side of the staple portions, as recited in column 9.

Regarding claim 47, Berg et al. disclose that as applied to claim 1, as well as, tapering of each staple portion that results in a reduction of radial thickness of a part of the staple portion, relative to a radial thickness of another part of the staple portion, as recited in column 9.

Regarding claim 48, Berg et al. disclose that as applied to claim 1, as well as, tapering of each staple portion that results in a reduction of circumferential width, respectively, of another part of the staple portion, as discussed throughout and seen in figure 21 for example.

Regarding claim 49, Berg et al. disclose that as applied to claim 1, as well as, tapering of each staple portion that results in a reduction of both a radial thickness and a circumferential width of part of the staple portion, relative to a radial thickness and a circumferential with, respectively of another part of the staple, as discussed throughout and seen in figure 21 for example.

Regarding claim 50, Berg et al. disclose that as applied to claim 6, as well as, a laser that is employed to make the connector, as recited in column 4, lines 18-23.

Regarding claim 51, Berg et al. disclose that as applied to claim 6, as well as, electric erosion that is employed to make the connector, as recited in column 4, lines 18-23.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

> be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. in US Patent No. 6,391,036 in view of Lazarus in US Patent No. 5,104,399.

Berg et al. disclose that as applied to claim 1. However Berg et al. do explicitly recite an annular member having sinusoidal pattern meandering about a circumferential line through the main plane of the annular member or each staple-like element that is located at an apex of the sinusoidal pattern. On the other hand, Lazarus teaches the use of a sinusoidal pattern in figure 11. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Berg et al. to have an annular member having a sinusoidal pattern meandering about a circumferential line through the main plain of the annular member and have each staple-like element located at an apex of the sinusoidal pattern, as taught by Lazarus for the purpose of enhancing expandability.

10. Claims 44, 45, and 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. in US Patent No. 6,391,036.

Berg et al. discloses that as applied to claims 40 and 6 as well as photo-etching and electroplating. However, Berg et al. do not explicitly recite tapering of the at least one staple portion that causes the at least one staple portion to

permanently deform to a B-shape in the joining position, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to an overlapping B-shape in the joining position, or a connector that is fabricated by making a two-dimensional shape from the single material and then forcing the two-dimensional shape into a three-dimensional shape. On the other hand, although not explicitly recited tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a B-shape in the joining position and tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to an overlapping B-shape in the joining position are well within the scope of the invention and obvious to one with ordinary skill in the art. As shown in figure 22 if the edges were further curled they would form a B-shape. Moreover, an overlapping B-shape is well within the scope of the invention analogous to that shown in figure 17. Moreover, a connector that is fabricated by making a two-dimensional shape from the single material and then forcing the two-dimensional shape into a three-dimensional shape would be an obvious method to make a tubular structure and well within the scope of the invention as discussed in column 4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

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